JUL 1 3 2001

K010600

Summary of Safety and Effectiveness
for
Suprema Powered Wheelchair

This safety and effectiveness summary for the Supreme Powered Wheelchair is provided as required per Section 513(i)(3) of the Food, Drug and Cosmetic Act.

1. Submitter :
Luigi Chinetti.
P.O. Box 292
East Haddam, CT. 06423
(860) 434-7165

Contact Person :
Luigi Chinetti
P.O. Box 292
East Haddam, CT. 06423
Telephone: (860) 434-7165

Date Prepared: January 17, 2001

2. Tradename: Suprema Powered Wheelchair
Common Name: Powered Wheelchair
Classification Name: Powered Wheelchair (890.3860)

3. Predicate or legally marketed devices which are substantially equivalent :

- OmegaTrac Powered Wheelchair (TefTec Mobility)
- Balder Electric Power Wheelchair (Balder USA)
- Quickie Model G-424 Power Wheelchair (Sunrise Medical)
- E-2000 Power Elevating Seat System (Accelerated Rehab Designs, Inc.)

4. Description of the device :

The Suprema Powered Wheelchair is a wheeled, battery-operated motor-driven chair for the disabled. Its compact size makes it particularly suitable for the work place and home. The armrests and footrests are adjustable. The seat can be tilted and elevated vertically to provide access to objects that would normally be unreachable. It incorporates joystick controls.

Materials: The devices are manufactured from stainless steel and aluminum alloy tubing, extrusions, castings and machined parts, with flame retardent cushions and upholstery components per ASTM and ISO standards.

Function: The wheelchair is intended to provide mobility to persons limited to a sitting position, that have the capability of operating a powered wheelchair.

5. Intended Use:

The Suprema Powered Wheelchair is indicated for use to provide mobility to persons limited to a sitting position, that have the capability of operating a powered wheelchair.

6. Comparison of the technological characteristics of the device to predicate and legally marketed devices :

There are no significant differences between the Suprema Powered Wheelchair and other wheelchairs currently being marketed which would adversely affect the use of the product. It is substantially equivalent to these other devices in design, function, material and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 3 2001

Mr. Luigi Chinetti
P.O. Box 292
East Haddam, Connecticut 06423

Re: K010600
Trade/Device Name: Suprema Powered Wheelchair
Regulation Number: 890.3860
Regulatory Class: II
Product Code: ITI
Dated: July 5, 2001
Received: July 6, 2001

Dear Mr. Chinetti:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known) : K010600

Device Name : Suprema Powered Wheelchair

Indications For Use :

The Suprema Powered Wheelchair is intended to provide mobility to persons limited to a sitting position that have the capability of operating a powered wheelchair.

FDA/CDRH/ODE/DHC
JUL 6 11 36 AM '01
RECEIVED

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription use ____
(PER 21 CFR 801.109)

OR

Over-the-counter use X____

(optional format 1-2-96)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010600